

Amendment to the Claims

The following list of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1-39. (Canceled)

40. (Currently Amended) A method for ~~diagnosis or monitoring of diagnosing~~ a hemostatic dysfunction comprising an inflammatory condition, said method comprising correlating the formation of a complex to a concentration of one or more lipoproteins comprising:

- a) ~~providing a test sample from a test subject;~~
- [[b]] a) adding at least one reagent comprising a divalent metal ion and at least one acute phase protein selected from the group consisting of C-reactive protein (CRP) and serum amyloid A to said ~~a~~ test sample ~~from a test subject~~ in order to cause formation of a complex of one or more lipoproteins selected from the group consisting of chylomicrons, very low density lipoprotein (VLDL) and intermediate density lipoprotein (IDL) and one or more acute phase proteins;
- [[c]] b) measuring the formation of the complex; and
- [[d]] c) correlating the formation of the complex to a concentration of said one or more lipoproteins that are observed in patients with said hemostatic dysfunction ~~to diagnosis or monitor the hemostatic dysfunction comprising the inflammatory condition,~~
wherein a greater formation of complex correlates to the presence of hemostatic dysfunction comprising an inflammatory condition.

41-42. (Canceled)

43. (Currently Amended) The method of claim 40, wherein said one or more lipoproteins is ~~chylomicrons, VLDL and/or IDL~~.

44. (Canceled)

45. (Currently Amended) The method of claim 40, further comprising correlating (i) the measured additional complex and (ii) the measured initial complex to a total amount of acute phase protein in the test sample. A method for monitoring hemostatic dysfunction comprising an inflammatory condition, said method comprising correlating the formation of a complex to a concentration of one or more lipoproteins comprising:

- a) adding at least one reagent comprising a divalent metal ion and at least one acute phase protein selected from the group consisting of C-reactive protein (CRP) and serum amyloid A to a test sample from a test subject in order to cause formation of a complex of one or more lipoproteins selected from the group consisting of chylomicrons, very low density lipoprotein (VLDL) and intermediate density lipoprotein (IDL) and one or more acute phase proteins;
- b) measuring the formation of the complex;
- c) correlating the formation of the complex to a concentration of said one or more lipoproteins that are observed in patients with said hemostatic dysfunction comprising the inflammatory condition; and
- d) forming an initial complex and an additional complex that are measured over time to provide respective first and second time-dependent measurement profiles, wherein (a) an increase in the slope of the second time-dependent measurement profile compared to the slope of the first time-dependent measurement profile correlates to a progression of the hemostatic dysfunction comprising the inflammatory condition, and (b) a decrease in the slope of the second time-dependent measurement profile compared to the slope of the first time-dependent measurement profile correlates to a regression of the hemostatic dysfunction comprising the inflammatory condition.

46. (Previously Presented) The method of claim 40, wherein the acute phase protein is C-reactive protein.

47. (Currently Amended) The method of claim 45 [[40]], wherein the measured initial complex is correlated to a likelihood of system failure and/or mortality and the greater the initial complex measured, the greater the likelihood of system failure and/or mortality.

48. (Canceled)

49. (Previously Presented) A method for testing the effectiveness of a therapeutic for treatment of hemostatic dysfunction, comprising:

- a) providing from a test subject a test sample to be tested for complex formation;
- b) adding one or more reagents which causes formation of a complex of acute phase protein and lipoprotein present in said test sample, wherein the reagent comprises a metal ion;
- c) administering to said test subject a therapeutic suspected of being useful in the treatment of hemostatic dysfunction;
- d) repeating steps a) and b); and
- e) determining if the amount of complex formed has changed, wherein a decrease in the amount of complex formed correlates to the effectiveness of the therapeutic for treatment of hemostatic dysfunction.

50-51. (Canceled)

52. (Previously Presented) A method for testing the effectiveness of a therapeutic for treatment of hemostatic dysfunction, comprising (a) monitoring the formation of a complex comprising C reactive protein (CRP) and at least one human lipoprotein selected from the group consisting of very low density lipoprotein (VLDL) and intermediate density lipoprotein (IDL), and (b) correlating the decrease of complex formation with effectiveness of a therapeutic for treatment of hemostatic dysfunction.

53. (Previously Presented) The method of claim 52, wherein the hemostatic dysfunction is disseminated intravascular coagulation (DIC).

54-55. (Canceled)

56. (Previously Presented) The method of claim 40, wherein the inflammatory condition is selected from the group consisting of an infection, sepsis, systemic inflammatory response syndrome (SIRS) and combinations thereof.

57. (Previously Presented) The method of claim 49, wherein the acute phase protein is C-reactive protein.

58. (Previously Presented) The method of claim 49, wherein the lipoprotein is chylomicron, VLDL and/or IDL.

59. (Previously Presented) The method of claim 49, wherein the metal ion is a divalent metal ion.

60. (Previously Presented) The method of claim 59, wherein the divalent metal ion is selected from the group consisting of calcium, magnesium, manganese, iron, barium and combinations thereof.

61. (Currently Amended) A method for diagnosis or monitoring of a diagnosing hemostatic dysfunction comprising an inflammatory condition, said method comprising correlating the formation of a complex to a concentration of one or more lipoproteins comprising:

- a) ~~providing a test sample from a test subject;~~
- [[b]] a) adding at least one reagent comprising a divalent metal ion and at least one acute phase protein selected from the group consisting of C-reactive protein (CRP) and serum amyloid A to said a test sample from a test subject in order to cause formation of a complex of one or more lipoproteins selected from the group consisting of chylomicrons, very low density lipoprotein (VLDL) and intermediate density lipoprotein (IDL) and one or more acute phase proteins;
- [[c]] b) measuring the formation of the complex;
- [[d]] c) correlating the formation of the complex to a concentration of said one or more lipoproteins that are observed in patients with said hemostatic

dysfunction, wherein the formation of an initial complex and the formation of an additional complex are measured over time to provide respective first and second time-dependent measurement profiles; and

- [[e]] d) ~~determining comparing~~ a slope and/or total change in the respective first and second time-dependent measurement profiles to ~~diagnosis or monitor~~ diagnose the hemostatic dysfunction comprising the inflammatory condition.

62. (Currently Amended) The method of claim 61, wherein said one or more lipoproteins is ~~chylomicrons, VLDL and/or IDL~~.

63. (Previously Presented) The method of claim 61, further comprising correlating (i) the measured additional complex and (ii) the measured initial complex to a total amount of acute phase protein in the test sample.

64. (Previously Presented) The method of claim 61, wherein the acute phase protein is C-reactive protein.

65. (Previously Presented) The method of claim 61, wherein the measured initial complex is correlated to a likelihood of system failure and/or mortality and the greater the initial complex measured, the greater the likelihood of system failure and/or mortality.

66-68. (Canceled)

69. (Previously Presented) The method of claim 61, wherein the inflammatory condition is selected from the group consisting of an infection, sepsis, systemic inflammatory response syndrome (SIRS) and combinations thereof.

70. (New) A method for monitoring hemostatic dysfunction comprising an inflammatory condition, said method comprising correlating the formation of a complex to a concentration of one or more lipoproteins comprising:

- a) adding at least one reagent comprising a divalent metal ion and at least one

acute phase protein selected from the group consisting of C-reactive protein (CRP) and serum amyloid A to said test sample from a test subject in order to cause formation of a complex of one or more lipoproteins selected from the group consisting of chylomicrons, very low density lipoprotein (VLDL) and intermediate density lipoprotein (IDL) and one or more acute phase proteins;

- c) measuring the formation of the complex;
- d) correlating the formation of the complex to a concentration of said one or more lipoproteins that are observed in patients with said hemostatic dysfunction, wherein the formation of an initial complex and the formation of an additional complex are measured over time to provide respective first and second time-dependent measurement profiles; and
- e) comparing a slope and/or total change in the respective first and second time-dependent measurement profiles to monitor the hemostatic dysfunction comprising the inflammatory condition, wherein (a) an increase in the slope of the second time-dependent measurement profile compared to the slope of the first time-dependent measurement profile correlates to a progression of the hemostatic dysfunction comprising the inflammatory condition, and (b) a decrease in the slope of the second time-dependent measurement profile compared to the slope of the first time-dependent measurement profile correlates to a regression of the hemostatic dysfunction comprising the inflammatory condition.